

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
16 May 2002 (16.05.2002)

PCT

(10) International Publication Number
WO 02/37935 A2

(51) International Patent Classification: Not classified

(21) International Application Number: PCT/US01/48416

(22) International Filing Date: 23 October 2001 (23.10.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/694,665 23 October 2000 (23.10.2000) US

(71) Applicants and

(72) Inventors: **KRAUSE, Norman, M.** [US/US]; 5544 Northumberland Street, Pittsburgh, PA 15217 (US). **WEISS, Lee, E.** [US/US]; 5600 Munhall Road, Apt. 402, Pittsburgh, PA 15217 (US). **SHIMADA, Kenji** [US/US]; 1704 La Costa Court, Pittsburgh, PA 15237 (US). **KANADE, Takeo** [US/US]; 130 Penrose Drive, Pittsburgh, PA 15208 (US).

(74) Agent: **KUCLER, Robert, D.**; Reed Smith LLP, P.O. Box 488, Pittsburgh, PA 15230-0488 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: COMPUTER-AIDED ORTHOPEDIC SURGERY

(57) Abstract: Devices and methods for implementing computer-aided surgical procedures and more specifically devices and methods for implementing a computer-aided orthopedic surgery utilizing intra-operative feedback. A three-dimensional model of an area of a patient upon which a surgical procedure is to be performed is modeled using software techniques. The software model is used to generate a surgical plan, including placement of multifunctional markers, for performing the surgical procedure. After the markers are placed on the patient, an updated image of the patient is taken and used to calculate a final surgical plan for performing the remainder of the surgical procedure. The three-dimensional modeling, surgical planning, and surgery may all take place remote from each other. The various entities may communicate via an electronic communications network such as the Internet.



WO 02/37935 A2

COMPUTER-AIDED ORTHOPEDIC SURGERY**PRIORITY**

5

**This Application Claims Priority to
U.S. Application No. 09/694,665 filed on
October 23, 2000**

FIELD OF THE INVENTION

The present invention generally relates to devices and
10 methods for implementing computer-aided surgical procedures and more
specifically relates to devices and methods for implementing a computer-
aided orthopedic surgery utilizing intra-operative feedback.

BACKGROUND OF THE INVENTION

Poorly aligned or misaligned bones can occur for a variety of
15 reasons including congenital deformity and/or accidental disfigurement. A
bone can be characterized as having an actual (or anatomical) axis that
runs through the cross-sectional center of the bone and a mechanical axis
that extends between the joints at either end of the bone and defines the
movement of the bone. In a generally straight bone with joints in line
20 with the anatomical axis, *e.g.*, the tibia with the knee and ankle joints, the
anatomical and the mechanical axes should almost coincide. In a non-
linear bone, *e.g.*, the femur with off-center hip joint, the mechanical axis
and the anatomical axis do not coincide even when the bone is correctly
aligned.

The essence of a bone deformity or disfigurement occurs when the anatomical axis is altered to a point that the mechanical (motion) axis is not in its desired position. In a straight bone such as the tibia, the amount of disfigurement can be calculated as the deviation
5 between the anatomical axis and the mechanical axis (because the axes should align in a straight bone). This deviation can cause discomfort, joint disease, decreased range of motion, and/or numerous other medical problems. To correct or limit these improper alignments, an orthopedic surgeon may perform corrective surgery on the deformed or disfigured
10 bone to return symmetry between the axes.

One type of corrective orthopedic surgery is an osteotomy. Osteotomies are characterized by cutting one or more slices into a deformed bone to a depth sufficient to allow the bone to be "repositioned" in a way that aligns the actual axis of motion with the desired axis.
15 Typically, the bone repositioning forms a "wedge" or gap of open space in the bone. This space is filled via bone graft to promote new bone growth, and some type of fixation mechanism is attached to the bone to keep the bone in its new (desired) orientation during the healing process.

The movement necessary to realign a disfigured or deformed
20 bone often requires solving complex planning calculations as well as using a certain amount of estimation based upon the experience of the orthopedic surgeon. To aid in the accuracy of this process, several types of Computer-Aided Orthopedic Surgery (CAOS) are currently being developed. In general, CAOS involves a three step process: (1) generating

a three-dimensional (3D) computerized model of the patient's bone; (2) performing a computer-aided pre-surgical analysis to generate a surgical plan that instructs a surgeon how to cut, fill, and/or reposition the bone as well as how to manipulate a robot during surgery; and (3) performing
5 computer-aided surgery based on the pre-surgical plan.

The current methods of modeling an incorrectly aligned bone often include the use of Magnetic Resonance Imaging (MRI) or Computerized Axial Tomography (CAT) data. These imaging technologies are very expensive and may take an extensive amount of time for which to
10 model a bone. Conventional CAOS methods often include robot-guided surgery or real-time tracking systems using highly technical equipment reserved for a few select surgeons in a very few locations. Therefore, a need has been recognized to provide the accuracy benefits of CAOS in a more cost effective, easy to use, and more widely available process than a
15 conventional CAOS procedure. This improved CAOS process is preferably available to a wider body of patients and surgeons spread across a greater geographic and economic spectrum than current methods.

SUMMARY OF THE INVENTION

20 The present invention contemplates, in at least one preferred embodiment, devices and methods for computer-aided orthopedic surgery. More specifically, the present invention contemplates devices and methods

for performing computer-aided surgical procedures, such as an open wedge osteotomy, using intra-operative feedback to improve the surgical outcome for the patient.

In at least one preferred embodiment of the present invention, a computer database includes one or more template bone models. Multiple X-rays of an incorrectly aligned bone are preferably taken and used to “morph” or modify a stored template bone model to create a 3D model of the misaligned bone. A computer program, running on a planning computer, may be used to aid in the generation of a pre-surgical plan for performing an osteotomy or other orthopedic surgery to correct bone alignment. The pre-surgical plan calculations may include: the positioning of multifunctional markers on the patient’s bone and the parameters for manipulating one or more surgical tools such as an adjustable cutting guide, an adjustable fixation guide, or a combined cutting-fixation guide.

During surgery, a surgeon preferably affixes multifunctional markers to the misaligned bone according to the pre-surgical plan. A new set of fluoroscopic or X-ray images may be taken and used by the planning computer to update the pre-surgical plan into a final surgical plan based on the actual marker positions as depicted in the fluoroscopy. In this way, the updated fluoroscopic or X-ray images act as an intra-operative feedback system.

The surgeon preferably follows the updated surgical plan to cut the bone guided by an adjustable cutting guide and reposition the bone using an adjustable fixation guide (or these guides could be combined) Additionally, for example, in an open wedge osteotomy, the gap between
5 cut sections of the bone are filled by bone graft and a fixation plate is attached thereto to hold the bone in its new orientation.

In at least one preferred embodiment, the planning computer exists at or near the same location as the surgical operating room. In other embodiments, the planning computer, template bone model
10 database, operating room, and any other possible computers or devices may be located remotely from each other. These devices are preferably connected electronically, *e.g.*, by way of the Internet. Such a distributed network allows access to the computer-aided osteotomy resources by an increased number of patients and surgeons than conventional methods.
15 For example, this distributed system may be used to remotely access other experts, such as experienced orthopedic surgeons, during the planning or surgical stages.

These and other details, objects, and advantages of the present invention will be more readily apparent from the following
20 description of the presently preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention and its presently preferred embodiments will be better understood by reference to the detailed disclosure hereinafter and/or to the accompanying drawings, wherein:

5 **Figure 1** shows a typical poorly aligned bone with reference axes;

Figure 2 is a block diagram of Computer-Aided Orthopedic Surgery (CAOS) methods including a general flow chart (2A), current methods (2B), and one embodiment of the present invention (2C);

10 **Figure 3** details the bone modeling process including patient bone X-ray and segmentation (3A), template bone model (3B), localized MRI (3C), and the resulting fused image (3D);

Figure 4 details the pre-surgical planning process including the calculation of the bone cutting area (4A), bone wedge opening (4B),
15 and placement of the multifunctional markers (4C);

Figure 5 details the offset analysis of a single osteotomy procedure;

Figure 6 details the offset analysis of a double osteotomy procedure;

Figure 7 details the multifunctional marker registration process including a calibration grid (7A), fluoroscopic image during surgery (7B), and resulting updated marker position bone model (7C);

Figure 8 details a top (8A) and isometric (8B) view of an adjustable cutting guide including exemplary surgical plan (8C) and a front view of the cutting guide mounted to the multifunctional markers (8D); and

Figure 9 details an isometric view (9A) of an adjustable fixation guide including surgical plan (9C) and a front view of the fixation guide mounted to the multifunctional markers with attached fixation plate (9B).

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention broadly contemplates, in at least one preferred embodiment, a device and method for performing computer-aided surgery. The present invention may be specifically suited for performing computer-aided orthopedic surgery, such as an osteotomy, on a misaligned bone. The following description provides an example of using the present invention to perform an open wedge osteotomy, but the invention can be used for many types of orthopedic and other surgeries.

Any reference to an open wedge osteotomy in particular is only by way of example.

FIG. 1 schematically shows an improperly aligned femur **10** and the resulting incorrect leg alignment. The **FIG. 1** actual mechanical axis **22** represents the axis of motion from the hip joint **12** to the middle of the tibia **18** (near the ankle). If correctly aligned, this axis **12** should pass very close to the midpoint of the patella or kneecap **14** (shown as the desired mechanical axis **20**). In the **FIG. 1** example, there is a deviation **24** between the desired **20** and actual **22** axes of motion. This deviation **24** represents the amount of femur **10** misalignment and can cause discomfort with decreased range of motion as well as other problems.

To correct these deformities, an orthopedic surgeon may perform an osteotomy or other surgery on the disfigured bone to return symmetry between these axes. Osteotomies are characterized by both the type of cut that is made in the bone (e.g., open wedge, closed wedge, center wedge) and the number of osteotomy sites (e.g., single, double). One type of osteotomy, an open wedge osteotomy, involves making a cut or wedge in the misaligned bone generally perpendicular to the long axis of the bone. Thereafter, depending on the desired bone realignment, the bone may be bent, twisted, and/or rotated about the cut sections until the "new" anatomical axis is properly aligned with the desired mechanical axis. Some type of fixation device, such as an internal plating system, may be used to hold the bone in its new orientation during the healing process

after proper alignment is achieved, and a bone graft is used to fill in the open wedge to promote new bone growth.

As briefly described above, the movement necessary to realign a disfigured bone may be quite complex (movement around many different axes) and may require the solution of complex planning calculations as well as a certain amount of estimation based upon the experience of the orthopedic surgeon. To aid in the accuracy of this process, several types of Computer-Aided Orthopedic Surgery **50** (CAOS) have recently been researched. In general, as seen in the flow chart of **FIG. 2A**, CAOS **50** involves a three step process: (1) generating a 3D computerized model of the patient's bone **52**; (2) performing a computer-aided pre-surgical analysis to aid in the creation of a surgical plan **54**; and (3) performing computer-aided surgery based on the pre-surgical plan **56**.

Traditionally, as shown in **FIG. 2B**, the 3D computerized bone model is generated from MRI or CAT data **58** for the patient's bone. Use of the MRI or CAT data **58** may produce an accurate 3D computer model of the bone, but these techniques are expensive and typically require an extended amount of time to perform the MRI/CAT procedure and to model the bone. Also, although generally available, the equipment necessary to perform these procedures may not be found in smaller hospitals or remote areas. Therefore, the use of these 3D modeling techniques, even when accurate, may require a patient to go through the time and expense of traveling to a different hospital.

Once a 3D computerized bone model is generated, computer vision, Virtual Reality (VR), Computer Aided Design/Computer Aided Manufacture (CAD/CAM), numerical optimization, artificial intelligence (AI), and/or other techniques and technologies **60** may be used to help

5 analyze the modeled bone and form a stepwise plan to carry out the surgery in the operating room. For example, a software program may compare the 3D model of the misaligned bone with existing models of properly aligned bones. The program may then determine, along a variety of different axes, an amount the bone needs to be moved in each direction.

10 Alternatively, the program may just analyze the actual and desired positions of the joints (*e.g.*, hip, knee, and ankle) to aid in the determination of where to cut the bone for the osteotomy and how to reposition the bone.

The result of any of these procedures will preferably be a set

15 of instructions or guidelines for the orthopedic surgeon to follow during surgery. The surgical plan may also calculate the positioning of one or more surgical tools or bone markers to be used during the procedure. Alternatively, the surgeon may be provided with a range (*e.g.*, within 2 mm. of a certain position) of acceptable choices. The surgical plan will

20 also preferably guide the surgeon in relocating or repositioning the misaligned bone. This part of the plan will preferably detail for the surgeon various distances and rotation angles through which the bone should be moved.

The surgical plan may be sent to the surgeon using various media types including: still images and illustrations; static CAD models and/or interactive CAD models; computer animations; video or movie presentations; text descriptions including cutting locations and angles and settings for surgical tools; rapid prototype models, or some other media type. The surgeon preferably reviews the plan and determines whether or not the surgeon is comfortable with performing the surgery according to the plan. If the plan is not acceptable, the surgeon preferably provides feedback and suggestions about the plan to aid in the development of a new plan. This process may repeat until the pre-surgical plan is acceptable to the surgeon.

After the surgical plan is reviewed, a computer-aided surgery may be performed by a variety of methods. For example, in FIG. 2B the surgery may be performed using robotic aides 62 or some type of infrared (IR) tracking device 64. One type of robot-aided surgery employs robots with touch sensors that register a patient's actual bone geometry during surgery. This actual geometry is compared with the 3D pre-surgical bone model to give feedback to the robot or surgeon while performing the surgery. This feedback allows a robot or surgeon to follow the surgical plan more accurately than without the sensors.

Alternatively, an IR marker system could be used during surgery. For example, IR markers may be attached to the patient's bone and to the surgical tools at various locations. A real-time IR sensing system may track these markers and register them to the pre-surgical 3D

model to provide feedback to the surgeon or to guide the surgeon to make precise surgical cuts according to the pre-surgical plan. Again, this feedback allows the surgeon to more accurately follow the surgical plan.

As with the full MRI or CAT data modeling **58**, this real-time
5 sensing and tracking of bone geometry using robotic aides **62** and/or IR
sensing systems **64** is expensive, and only the most well-funded hospitals
can afford the technology. Furthermore, many surgical procedures
require computerized models of the entire limb (*e.g.*, both the femur and
the tibia of the leg) for generating the surgical plan, and acquiring
10 MRI/CAT images of entire limbs may be both time-consuming and
expensive.

Lower cost and more efficient and/or accessible surgical
planning and performance methodologies are always desired. The present
invention may improve upon conventional CAOS methods by replacing
15 one or more of the above steps. For example, the MRI/CAT 3D-modeling
step **58** and the computer-guided surgical procedures **62**, **64** may be
replaced with more cost effective and/or quicker approaches. The entire
CAOS process **50** may be simplified and made more accessible for patients
and surgeons by using less complex equipment and by locating certain
20 computer equipment and planning resources in a centralized location.

The following example of the present invention describes
using a planning computer and bone model database to generate a
surgical plan for performing an orthopedic surgery. Much of the software

involved, including the algorithms for generating a 3D model of the patient's bone were previously discussed in U.S. Patent Application No. 09/545,685 filed April 7, 2000 entitled "Computer-Aided Bone Distraction" which is commonly owned with the present invention and is
5 expressly incorporated by reference in its entirety herein. The following discussion will highlight the relevant portions of the previous application but will focus on previously undisclosed features.

In one aspect of the present invention, the 3D pre-surgical models of the misaligned bones may be created directly from readily
10 available and inexpensive regular X-ray images **66**. Initially, a 3D model of a "normal" or properly aligned reference bone may be generated. This "template bone model" or template bone model CAD data may be generated based on representative bone topographies from MRI or CAT data, or data from any other imaging technique. The template bone model
15 may then be stored in a computer database for future access. The template bone model database preferably stores various different template bone models to be used for patients of different ages, genders, heights, and other characteristics. Alternatively or additionally, the bone models may be scalable or otherwise alterable to generate various-sized bone models.
20 Once created and stored, each template bone model in this family of bone models can be used repeatedly and even shared among various surgeons, technicians, hospitals, or other interested users.

Preferably, each of these 3D template bone models **88** can be graphically projected onto planes to produce a template bone model in a

two-dimensional plane 84, 86 (see FIG. 3B). By projecting the 3D template bone model into at least two flat planes, preferably two planes that are orthogonal to each other, the template database or other computer can represent a bone as a series of two-dimensional pictures.

5 An AP and lateral image projection of the template bone may be preferred. These two-dimensional projections may then be compared to X-rays or fluoroscopic images of a patient's bone to determine proper alignment. These template bones may exist in a computer database or other storage medium and can be shared, electronically or physically, with the users of

10 several surgical planning computers.

The equipment used to generate the two- and three-dimensional template bone models is preferably a computer with advanced imaging and storage capabilities. The software algorithm is preferably able to convert the MRI, CAT, or other imaging data into a 3D

15 "virtual" representation of the bone, as well as several flat projections of the bone. The template bone model preferably includes 3D positioning and scaling parameters as well as free-form deformation parameters as discussed in U.S. Patent Application No. 09/545,685 . These parameters allow the template bone model to be reshaped or "morphed" to resemble

20 the patient's actual bone. This modeling computer may exist separate from the planning computer (see below) and/or any other device, or the modeling and planning computers may be integrated into one unit.

Once the template bone model has been created, the surgeon or technician may prepare a 3D software "model" of the patient's

misaligned bone. Rather than generating the 3D model of the improperly aligned bone directly from MRI or CAT data as performed by conventional systems, the surgeon or other technician may alternatively use several regular X-ray images of the patient **66** (which are typically taken before
5 any surgery). Preferably, at least a lateral and an AP (anterior-posterior) X-ray are taken of the patient's bone. The result of this imaging procedure is a series of two-dimensional representations of the patient's bone from various angles.

As shown in **FIG. 3A**, a software or other method may be
10 used to segment **80** the patient's bone **82** in the X-ray images **83**. Segmentation is characterized by determining the outer bounds **80** of the bones **82** in the X-rays **83**. Segmentation may be accomplished using a light board and digitizing stylus. Because the AP, lateral and any other X-rays **83** are preferably taken orthogonal to each other, the resulting
15 segmented bone represents a projection of the patient's bone on orthogonal planes similar to the two-dimensional orthogonal planes of the template bone models just described.

A software program or other method may analyze the X-rays of the patient's bone and compare it to the projections **84**, **86** of the 3D
20 template bone model **88** (**FIG. 3B**). If the template database contains more than one set of template bone models, the software may select the template bone model that most closely matches the patient's bone. The selection of a template bone model may occur based on patient history, or the selection may be based on comparing the patient X-rays **83** with two

dimensional projections 84, 86 of the 3D template bone model 88. The software then determines how the template bone model should be altered to more accurately depict the patient's actual misaligned bone.

5 A "morphing" software program may be used to alter, bend, or morph the selected template bone model 88 in a way that causes the projections 84, 86 of the template bone model 88 to more closely match the two-dimensional segmented bone images 80 from the patient's X-rays 83. In effect, the 3D template bone model 88 is reshaped to resemble the patient's actual bone 82. The result of this process is a computer-modeled
10 3D representation of the patient's bone 89. The template bone model selection and morphing process may be performed on the modeling computer, the planning computer, a separate computer, or some combination of the three.

In a preferred embodiment of the present invention, the
15 morphing software may alter the 3D template bone model 88 in small iterations until the projections of the 3D bone model 84, 86 match the X-ray or other images 83 of the patient's bone. For example, once an appropriate 3D template bone model 88 is chosen, the software may analyze the differences between the two-dimensional projections of the 3D
20 template bone model 84, 86 and the segmented images 80 of the patient's bone. The software may then alter (stretch, bend, etc.) the 3D template bone model 88 in such a way that the template bone model projections will more accurately resemble the patient's X-ray images. The projections of the altered template bone model may then be compared to the X-ray

images again. If the projections and the X-rays are not yet sufficiently similar, the software preferably alters the 3D bone model again to achieve similarity. The newly altered bone model may then be projected and compared to the patient's X-ray images another time. This process
5 preferably continues until the 3D bone model has been altered sufficiently to make the projections match the patient's X-rays. When sufficient similarity occurs, the altered 3D bone model (3D patient bone model 89) should resemble the patient's actual bone.

This iterative reshaping may include a two-step process as
10 described in U.S. Patent Application No. 09/545,685. For example, the positioning and scaling parameters may be optimized by rigid motion and scaling. An additional level of free-form deformation may be added for additional accuracy. As each iteration is completed, the 3D CAD data that defines the 3D patient bone model is preferably updated.

15 It should be noted here, that constructing a 3D patient bone model based on a pair of two dimensional X-rays will not typically result in a perfect representation of the patient's bone. The accuracy of the model is limited by geometric laws. In essence, the software algorithm described above codifies and improves upon the very method that a
20 surgeon uses when looking at the same X-rays and then forming a mental picture of the patient's bone before surgery. The computer algorithm improves precision and makes this process easier for surgeons.

The “morphed” 3D patient bone model **89**, which now portrays the patient’s bone, can be used to provide gross information about the alignment of the bone’s mechanical and anatomical axes. In some cases, this bone model information may not be of sufficiently high fidelity or quality to accurately model the more geometrically complex areas of the bone, *e.g.*, the joints at the ends of the bones. This gross information may also not properly show the “twists” in the bone such as the relative orientation between the hip socket and the head of the femur. In these cases, more accurate, local models of the joints or other bone areas can be derived from fusing selective volumetric MRI/CAT scan data **90** for the joints with the morphed model **89** (*see* FIGS. 3C-3D). Portions of the 3D patient bone model may be reconstructed or refined using selected MRI cross-sectional slices of the patient's bone **90**, or portions of the bone model may be completely replaced with the MRI data.

FIG. 3C shows a “local” MRI **90** taken at the bottom of the femur to augment and clarify the morphed bone model **89** at an area of bone surface complexity. However, if the localized MRI information is not available, the morphed bone can still be used with the present CAOS invention as an improvement over current methods.

The result of this process is preferably a 3D software model **92** (based on 3D CAD data) of the patient’s bone that is sufficient for computer-aided planning of the orthopedic surgery or other procedure. In contrast to conventional methods, this model **92** is preferably created using normal patient X-rays **83** and pre-existing template bone models **88**

that may be generated once and then shared among various users at different imaging locations. This method may decrease the amount of time and money spent generating the 3D software model **92** of the patient's misaligned bone.

5 In addition to the 3D patient bone model **92** created on the computer, a rapid prototype model of the bone could be created using the stored 3D CAD data. The rapid prototype model is an actual, physical model of the bone made using conventional CAD/CAM or other modeling techniques. This rapid prototype model may be given to the surgeon to
10 allow the surgeon to better visualize the misaligned patient bone before and even during surgery.

 After the morphed 3D patient bone model **92** is generated, CAOS planner software developed as part of the present invention, may initially determine the osteotomy site location on the model.

15 Alternatively, the surgeon may draw on his experience to choose a location for the osteotomy, and the location may be further optimized by the CAOS planning software. In some osteotomy procedures, the patient's bone may be so poorly aligned that a multiple osteotomy is needed to restore alignment to the bone. In these multiple osteotomies, the planning
20 computer may be especially useful because of the complexities of the 3D model.

 The CAOS system preferably includes a planning computer that may or may not include the database of template bone models **88**, the

computer that modeled the original template bone models **88**, or the computer that morphed the template bone model **88** to create the patient bone model **89**. **FIGS. 4A** and **4B** show a rudimentary determination of the proper osteotomy procedure. In **FIG. 4A**, the planning computer
5 software analyzes the alignment of the leg bones **100** and the present mechanical axis of motion **104** (the dotted line from the ball joint in the hip to the bottom of the tibia in the ankle). **FIG. 4A** depicts the software's determination of a cutting location **102**, and **FIG. 4B** depicts an opening "wedge" angle **106** as a possible solution that realigns the mechanical
10 axis **107** through the middle of the patella.

There may be different software algorithms used for the various types of orthopedic surgeries. For a "simple" single osteotomy, the software algorithm may utilize the steps as set forth in **FIG. 5**. The single osteotomy entails locating an optimum place to cut the bone which limits
15 the amount of bone movement needed to realign the bone during surgery.

FIG. 5A shows a 3D bone model **121** of a patient's misaligned bone. The planning software may initially determine an anatomical axis **122** through the center of the bone model **121**. The computer may also calculated an existing mechanical axis **124** defined
20 from the midpoint at one end of the bone down to the midpoint of the other end of the bone. The software algorithm preferably also calculates a desired mechanical axis **126** that will extend between the midpoints of the two ends of the bone after the osteotomy is performed. This desired mechanical axis **126** should begin at the existing midpoint of one end of

the bone (shown extending from the lower end of the bone in **FIG. 5A**), and extend along the intended orientation of the bone.

The objective of the planning software is to determine at what location to cut the bone so that the relocation of the bone from its present mechanical axis **124** to the desired mechanical axis **126** is at a minimum. To accomplish this task, the anatomical axis **122** of the bone is preferably sliced or segmented at regular intervals **120** throughout the 3D model. These slices **120** are preferably taken perpendicular to the anatomical axis **122** of the bone **121**. In the **FIG. 5A** example, there are 20 slices **120** taken.

The planning computer then preferably “virtually” cuts the bone model **121** at each of these 20 slice locations **120** and moves the upper section of the bone until the midpoint of the upper end of the bone is aligned with the desired mechanical axis **126** (**FIGS. 5B-5C**). The planning software may then compare the “new” midpoint (anatomical axis) of the bone section just above the bone slice **132** with the position of this same point before the relocation **133**. The distance between these two points **132, 133** is the deviation that now exists between the upper and lower bone segments in **FIG. 5C**. The planning computer preferably calculates this deviation distance for each of the 20 (or any number) of slice **120** iterations and determines which osteotomy location has the smallest deviation (all deviations shown as **130**). This location is preferably chosen as the preliminary site of the osteotomy.

A more complicated software methodology may be employed to perform the predictive analysis of the osteotomy. For example, a “rough” analysis to determine general location could then be followed up with a more refined analysis in the general vicinity of the predicted
5 osteotomy location. Also, additional slices could be used for better resolution.

FIG. 6 shows a possible software methodology for use with a double or multiple cut osteotomy planning procedure. The axes **144**, **148**, **150** and slice locations **142** in this method are preferably determine in the
10 same way as the single osteotomy. However, the planning software may now perform a more complicated predictive analysis.

FIG. 6A shows that the same 20 virtual slices **142** are taken as in the single osteotomy procedure. However, the planning software preferably goes through all possible iterations of osteotomy locations.
15 With a single osteotomy and 20 slices **142**, there are 20 iterations. With a double osteotomy and 20 slices, there are just under 200 unique iterations (discounting the iterations that would duplicate the same osteotomy locations but in a different order).

For example, the planning software may start from the first
20 slice location and “perform” a first virtual osteotomy (**FIG. 6A**). Thereafter, the planning software may calculate a second osteotomy performed from each of the other 19 slice locations. To calculate the effect

of the osteotomy, the planning software preferably adds the deviation of the anatomical axes for both osteotomies together.

After these 19 (or any number) iterations have been modeled and the deviation results have been calculated, the planning computer
5 preferably moves the first osteotomy location to the second slice and continues the analysis. The second osteotomy is preferably "made" at the other 19 slice locations, and the deviation results of the two cuts are preferably added to determine a total deviation.

After all 20 of the slice locations have been modeled with the
10 other 19 slice locations for a second cut, the planning software preferably plots the results on a 3D diagram. For example, the X and Y axes could represent the first and second slice locations, and the Z axis could plot the total deviation at these two osteotomy locations. By examining the diagram, and looking for a Z axis minimum, the planning computer or
15 surgeon may easily determine the appropriate locations for the double osteotomy or other multiple orthopedic procedures.

Although a surgeon may be able to visualize in his or her head the appropriate location for a single osteotomy, a double or higher order osteotomy, as shown in **FIGS. 6B-6C**, may be too complicated for
20 such human analysis. In these cases, the CAOS method of the present invention may be especially useful.

After determining the proper procedure location, the computer-based planning software places multifunctional markers 110 near the suggested osteotomy location 102 on the computerized 3D patient bone model 100 (*see*, FIG. 4C). The multifunctional markers 110 may be used to both register bone location during surgery and anchor various surgical guides (*e.g.*, a cutting guide to open the bone, a fixation guide to reposition the bone in the desired orientation during surgery, or a combined cutting-fixation guide). The optimizer or planning software may determine the appropriate location for the markers 110 based on mechanical tolerance data for the surgical guides that will be used during the surgery. Preferably, the guides and markers 110 have already been modeled by the planning computer. These multifunctional markers 110 may be detected during the surgery by X-ray, fluoroscopy, or other imaging methods to increase procedure accuracy over conventional surgical methods. The computer may provide an exact preferable location in which to place the markers 110, or the computer may offer a suggested range of marker positions (an allowable work envelope) within an acceptable tolerance limit.

Based on the computer-aided marker placement position, the planning computer preferably generates a “preliminary” surgical plan for the surgeon to follow in the operating room. This surgical plan may help the orthopedic surgeon decide whether or not to perform the surgery, and the plan may be used in the event the final surgical plan (explained below) is lost or electronically unavailable during surgery. This preliminary

surgical plan preferably includes step-by-step guidelines for performing the orthopedic surgery. For example, the surgical plan may include various translation and rotation settings for an adjustable cutting guide used to locate and hold a reciprocating saw during surgery. Because the
5 planning computer has previously calculated the location of the markers, and further because the adjustable cutting guide is anchored to the multifunctional markers during surgery, the cutting guide "settings" can be pre-calculated as part of the preliminary surgical plan. During the actual surgery, the surgeon need only set the cutting guide according to
10 the plan and attach the guide to the markers (or attach the guide to the markers and then adjust the guide settings).

The planning computer may also calculate a pre-surgical plan for an adjustable fixation guide. This guide, which is preferably used to open the osteotomy wedge and reposition the incorrectly aligned bone,
15 may also be anchored to the multifunctional markers. Because the marker position has previously been determined, the planning computer can also predetermine the fixation guide settings.

In an alternative embodiment, the cutting, fixation, or combined cutting-fixation guides may attach directly to the bone without
20 the use of multifunctional markers. Preferably, these guides will be adapted for direct mounting to the bone using an adhesive, screw, or other device. Moreover, as described below, the present invention may be used when these guides are attached without the use of a pre-surgical plan, for example after a trauma. Images may be taken of the bone with attached

guides, and a "final" surgical plan could be developed without the pre-surgical plan.

Once a planning computer has either modeled or simulated the osteotomy procedure, or has developed a detailed preliminary surgical plan, the simulation and/or plan is preferably sent to the surgeon to determine if the procedure will be performed. The surgical plan may be sent to the surgeon using various media types including: still images and illustrations; static CAD models and/or interactive CAD models; computer animations, video or movie presentations; text descriptions including cutting locations and angles and settings for surgical tools; rapid prototype models, or some other media type. The surgeon can preferably view the 3D computer simulation or other plan of the surgery and decide whether or not the plan is acceptable. If the surgeon does not "accept" the plan in its current embodiment, the surgeon may provide suggestions or comments that are sent back to the planning computer operator or to the surgical expert counseling the planning computer operator. The simulation and acceptance of the surgery may occur before a detailed preliminary surgical plan is developed, or the plan may be presented to the surgeon so they can proceed with the proposed plan or offer a new plan.

Once the patient's bone has been properly modeled and/or a preliminary surgical plan has been developed, the patient is ready to undergo the actual orthopedic surgical procedure. During surgery, radio-opaque multifunctional markers **110** are preferably attached to the

patient's bone as both a location mechanism and as an anchor for the surgical guides (*e.g.*, a cutting guide, fixation guide, combined cutting-fixation guide, and/or a calibration grid). These markers 110 may be small blocks that include a screw for mounting the markers to the bone and a screw acceptor (threaded hole) for attaching one or more guides thereto. Alternatively, the markers may be a threaded pin that is inserted into the patient's bone. Various surgical tools could be clamped to the end of the pin extending out of the bone during surgery.

At the beginning of the surgery, the surgeon is shown a CAD display or other representation of the pre-surgical plan depicting the required location/orientation of the osteotomy and the *ideal* location (and/or a tolerance zone) for the markers 110 to be placed on the patient's bone. The surgeon then exposes the patient's bone at the general location of the intended osteotomy and manually inserts the markers onto the bone (*e.g.*, by screwing the markers into the bone) in *approximate* locations above and below the intended osteotomy. Because of the inherent inaccuracies associated with a surgeon trying to duplicate the location seen on a "picture" of the bone, the markers may or may not be placed in the *exact* desired location. Because of the accuracy of the plan, the surgeon may generally perform a minimally invasive surgery using a smaller incision than conventional methods.

In attaching the multifunctional markers to the patient's bone, it is preferable to align the axes that extend vertically through the top of the two markers (axes 111 in FIG. 4C) so that these axes are

parallel to each other. If these axes are parallel, the markers 110 are "in the same plane" which will make mounting the various guides to the markers easier. This may also make the guides simpler to design as fewer degrees of freedom for placement are needed. To accomplish this

5 alignment, a marker insertion guide (not shown) may be used to align the markers during positioning on the patient's bone.

The marker insertion guide is preferably a hollow metal tube with jagged edges towards one end. The jagged edges can "grab" the bone and secure the hollow tube while a drill bit is extended through the tube.

10 The tube acts as a guide to make sure the markers are attached in the same plane. Various types of marker insertion guides are well-known in the medical arts.

After the markers 110 are attached, a translucent calibration grid 170 (with radio-opaque grid points or gridlines 172 printed thereon)

15 may be mounted around the patient's bone (FIG. 7A). The calibration grid 172 preferably consists of two orthogonal grid sheets that are mounted around the outside of the surgical area such that they are parallel to the image plane of a lateral and AP fluoroscopic image of the misaligned bone. For example, the grid 170 may be mounted to the

20 multifunctional markers 110. Upon imaging, the two-dimensional planar image 174 of the bone is set against the backdrop of the grid points 172. These grid points 172 are used to more accurately determine the positioning of the markers 110 and other areas of the bone by providing a background reference to aid in the "unwarping" of the fluoroscopic image.

After the calibration grid **170** is secured in place, one or more fluoroscopic images **174** are obtained for the exposed bone area including the attached calibration grid **170**. Preferably, at least a lateral fluoroscopic image and an AP fluoroscopic image are obtained (**FIG. 7B**).

5 A fluoroscopy is a low radiation imaging device that can be more flexible and useful in certain situations than obtaining X-ray images. A fluoroscopy machine is generally more maneuverable as compared to the bulkier and more cumbersome X-ray machine. However, fluoroscopy is often susceptible to image warping effects (*see, e.g., 176*) caused by

10 surrounding magnetic or electromagnetic fields, sagging of the imaging source or other interference. The warping **176** of a fluoroscopic image of an object distorts the image. Therefore, image translation and further “unwarping” may be performed to remove or minimize resulting distortion **176**. This type of fluoroscopic image correction is well-known in

15 the art and is typically corrected using software techniques. The “warped” calibration grid points in the fluoroscopy can be used to unwarped the fluoroscopy image. When the imaged grid points are straight, the image has been unwarped correctly.

The corrected fluoroscopic image is generated on or sent to

20 the planning computer, to determine the location of the markers **110** as precisely as possible in relationship to the 3D bone model. (**FIG. 7D**) The “new” or updated multifunctional marker position analysis may help negate the inherent problems with actual marker positioning (*e.g., not being able to accurately place the markers according to the plan*). The

planning computer software preferably updates the locations of the earlier placed markers **110** on the 3D patient bone model **100** to reflect the actual marker locations on the patient's bone. With this updated information, the planning software may then *re-calculate* the pre-surgical plan settings
5 for the cutting guide, fixation guide, combined cutting-fixation guide, and any other device used during the surgery. In essence, the pre-surgical plan may be updated to correct the inherent errors in placing the markers by hand during surgery. Using this intra-operative feedback during the surgery, a more accurate surgical plan can be calculated by the planning
10 computer.

After the new or "final" surgical plan is calculated, the surgeon is ready to actually perform the osteotomy. The osteotomy preferably begins by cutting the bone so that the bone can be repositioned according to the desired axis of motion. The bone is typically cut using a
15 reciprocating or "gigley" hand-held saw that is less damaging to surrounding tissues and cells. To more accurately control the cut made by the reciprocating saw, an adjustable cutting guide **190**, such as the one shown in **FIG. 8A**, may be used.

FIG. 8A details a top view and **FIG. 8B** shows an isometric
20 view of a manually adjustable cutting guide **190** that may be mounted onto the multifunctional markers **110** secured to the patient's bone **100**. The cutting guide **190** is comprised of a base plate **192** and a cutting guide member **194**. The base plate **192** preferably has two anchor slots **202**, **204** through which a screw or other attachment device may be inserted so that

the adjustable cutting guide **190** can be secured to the multifunctional markers **110** on the patient's bone **100**. The base plate **192** may also include two adjusting slots **196, 198** for setting the proper positioning of the cutting guide member **194**. The two adjusting slots **196, 198** are
5 preferably marked with indicators **206, 208**, in this case numbers, that correspond to the surgical plan that the planning computer outputs for the surgeon.

The cutting guide member **190** includes two screws **210, 212** or other adjusting devices that are integrally located within the adjusting
10 slots **196, 198**. In the center of the cutting guide member **194**, there is preferably a saw slot **200** that can be rotatably adjusted to accommodate a reciprocating saw at a variety of angles for cutting the patient's bone.

In practice, the adjustable cutting guide **190** may allow the surgeon to more accurately recreate a cut in the patient's bone as modeled
15 by the planning computer. Preferably, the surgical plan calculated by the planning computer, after being updated to reflect the actual positioning of the radio-opaque multifunctional markers **110** on the patient's bone, includes a preferred "setting" for the adjustable slots **196, 198**, as well as a preferred angle Φ for the saw slot **200**. One such example plan is shown
20 in FIG. 8C.

The slot settings **206, 208** for the adjustable cutting guide **190** are preferably used to locate, along at least two axes, the reciprocating saw used to cut the patient's bone. For example, by altering

the relative position of the slot settings with respect to each other, the cutting guide member 194 may be rotated in a plane perpendicular to the face of the patient's bone (looking down on the bone from above). If the right slot setting 206 is set to 5, and the left setting 208 is moved from
5 1 up through 12, the cutting guide member 194 will rotate in a clockwise direction. Because the left set screw 212 of the cutting guide member 194 preferably has a slotted opening rather than a simple hole (as on the right side 210), the cutting member 194 is preferably capable of being rotated. If both the left and right set screws 210, 212 of the cutting guide member
10 were in circular holes, the cutting guide member 194 would only be able to slide back and forth in the base member adjustable slots 196, 198.

In addition to setting the vertical rotation of the cutting guide member 194, the slot settings 206, 208 also determine at what location relative to the multifunctional markers 110 the cut should be
15 made. For example, if both slot settings 206, 208 are increased by the same amount, the cutting guide member 194 will slide up towards the top marker while maintaining the same rotational setting. Likewise, if the slot settings 206, 208 are decreased in equal amounts, the cutting guide member 194 will move towards the lower marker. Both slot settings 206,
20 208 are preferably manipulated and set via manual setting devices such as a set screw 210, 212 or small bolt used to tighten the cutting guide member 194 in the desired position. Because the surgical plan preferably displays the appropriate guide settings to the surgeon and the adjustable

cutting guide slots are pre-marked, use of the cutting guide may be quicker, easier, and more accurate than conventional methods.

The surgical plan also preferably includes an angle Φ for which the saw slot **200** is to be rotated and secured within the center of the cutting guide member **194**. As with the base plate slots **206**, **208**, the saw slot **200** is preferably pre-marked with angle demarcations (not shown) that allow for easy adjustment of the saw slot **200** to a desired cutting plane angle. The saw slot **200** may then be secured in a desired position by way of a set screw or some other temporary fixation device.

Once the three (or more) settings for the adjustable cutting guide **190** are set according to the updated surgical plan, the cutting guide **190** is preferably attached to the patient's bone **100** (or the guide **190** may be attached to the bone **100** before setting). Preferably, the base plate **142** of the adjustable cutting guide **190** includes two mounting slots **202**, **204** through which a screw or other mounting device can be inserted to affix the adjustable cutting guide **190** to the multifunctional markers **110**. The first mounting slot **204** is preferably a hole slightly larger than the mounting screw so that the cutting guide **190** is unable to slide with respect to the markers **110** during surgery. The second mounting slot **202** is preferably oval or slotted to accommodate a slight "misplacement" of the multifunctional markers **110** on the patient's bone **100**. Because the markers **110** may not be placed at exactly the desired distance apart from each other, the mounting slots **202**, **204** can preferably accommodate the markers **110** at slightly greater or smaller distances from each other.

FIG. 8D shows the adjustable cutting guide **190** mounted to the multifunctional markers **110** on an exposed bone **100** with the skin and other tissues removed for clarity.

After the adjustable cutting guide **190** is mounted to the bone **100**, the surgeon preferably inserts a reciprocating saw or other cutting device into the saw slot **200** of the cutting guide **190** and cuts the patient's bone **100** according to the surgical plan. The saw slot **200** may include a mechanical stop that prevents the saw from cutting a slot in the bone of more than the desired depth. After the osteotomy cut is made, the saw is removed from the cutting guide **190** and the cutting guide is dismounted from the bone **100** by unscrewing it from the multifunctional markers **110**.

After the cutting guide **190** is removed from the bone **100**, and with the multifunctional markers **110** still attached to the bone, the bone is ready to be bent, rotated, twisted, and/or repositioned into the proper alignment according to the updated surgical plan. The cut **102** in the bone **100** has been made, and the wedge may now be opened. **FIG. 9A** shows an exemplary adjustable fixation guide **220** for use in repositioning an improperly aligned bone. The purpose of the adjustable fixation guide **220** is preferably to force the bone **100** into the newly desired position with a greater amount of accuracy compared to conventional methods. Again, this part of the surgical plan has been "updated" based on the actual position of the multifunctional markers.

The adjustable fixation guide **220** pictured in **FIG. 9A** allows for movement of the bone along two axes: (1) lengthening the space between the two markers **234** and (2) rotating the two markers away from each other **232**. The fixation guide **220** is preferably made of two guide
5 arms **226**, **228**, two mounting tabs **223**, **225**, two base arms **222**, **224**, and a base shaft **230**. By manipulating the two guide arms **222**, **224** according to the surgical plan, the osteotomy wedge may be opened precisely according to the computer-calculated optimum position based on the updated location of the multifunctional markers **110**.

10 The two base arms **226**, **228** are preferably connected to each other by a base shaft **230** that runs at least partially into and through the middle of the base arms **226**, **228**. The base shaft **230** allows the base arms **226**, **228** to move translationally **230** (towards and away from each other down the long axis of the base shaft **230**) as well as rotationally **232**
15 (around the long axis of the base shaft **230**). At the opposite ends of the base arms **226**, **228** from the base shaft **230**, there are preferably two mounting tabs **223**, **225** and two guide arms **222**, **224**. The mounting tabs **223**, **225** provide a surface for securing the adjustable fixation guide **220** to the multifunctional markers **110**. For example, the mounting tabs **223**,
20 **225** may have a post or threaded shaft extending out from the bottom of the adjustable fixation guide **220** that can be inserted into the multifunctional markers **110**.

FIG. 9B shows the adjustable fixation guide **220** mounted on the multifunctional markers **110**. **FIG. 9C** shows an exemplary surgical

plan for manipulating the two guide arms 222, 224 in order to open the wedge 102 in the osteotomy. In this example, the translation is set to 5 and the rotation Φ is set to 15. These numbers can represent degrees, millimeters, are any other dimension, or may just represent position numbers labeled on the adjustable fixation guide 220. In any case, the surgical plan enables the surgeon to accurately manipulate the guide arms 222, 224 of the adjustable fixation guide 220 to open the bone wedge 102 or otherwise relocate the bone 100. The guide arms 222, 224 may be ratcheted to prevent the bone from closing if pressure is removed from the adjustable fixation guide 220.

FIG. 9B also shows a fixation plate 240 that may be used to hold the opened wedge 102 in the appropriate position while the bone 100 heals and rebuilds itself. The plate 240 may be a metal rectangle with two small holes drilled therethrough near the ends of the fixation plate 240. Preferably, while the adjustable fixation guide 220 is still connected to the multifunctional markers 110, the fixation plate 240 is secured to the open wedge-side of the bone 100. To aid in the healing process and to promote future bone growth, bone material from a bone graft may be inserted into the wedge 102 to fill in the empty space.

As stated above, it should be noted at this point that the above cutting and fixation guides are presented by way of example only. In practicing the present invention, these two guides may be combined into one cutting-fixation guide, or any number of other surgical tools or guides may be used. Likewise, the various surgical tools and/or

calibration guides could be attached directly to the bone, without the use of the multifunctional markers. In this embodiment, a fluoroscopic image of the attached tool could be captured during surgery to update the surgical plan. A number of different variations on these same themes, including methods without a pre-surgical plan, could be employed within the scope of the present invention.

If the osteotomy procedure of this example includes more than one cut, the other parts of the bone may be opened at this time. As with the first procedure, the markers are placed; a fluoroscopic image is taken; a final surgical plan is developed; and the bone is cut, opened, and realigned. To save time, the marker placement and fluoroscopy for both sets of cuts may be completed at the same time. Once the final surgical plan is generated, each cut may then proceed in turn.

After the open bone wedge **102** is filled and the fixation plate **240** is secured, the adjustable fixation guide **220** is removed from the multifunctional markers **110**. The markers **110** themselves are preferably removed from the patient at this point. However, in some applications of the present invention the markers may be necessary for a future surgery or adjustment and are not removed from the bone immediately after surgery. Specialized markers (not shown) may be needed if the markers are not removed. After removal, the surgical area is closed and the surgery completed. During recovery, additional X-rays or other images may be taken to determine if the osteotomy was performed successfully.

The above example described an embodiment of the present invention wherein the modeling computer, planning computer, and all necessary surgical equipment exist in the same location where the surgery is performed. A computer network, such as the Internet, may also be used
5 to connect the operating room equipment to the planning and other computer systems. In this way, one central planning computer location can serve a plurality of different operating rooms or different hospitals. Alternatively, one central modeling computer may contain a database of template bone models that are used by a variety of different planning
10 computers in a variety of different locations.

The entire CAOS process may occur as part of a distributed computer network. For example, the initial X-rays of the patient may be taken at a local hospital and then sent electronically to a modeling computer in a central location. The operator of the modeling computer
15 may search a local or remote database of template bone models to determine which model most closely resembles the patient's bone. Thereafter, the "morphing" of the model may take place on this same modeling computer, in this same location, or on a separate morphing computer at a different location.

20 Once the "morphed" patient bone model is generated, the model is preferably sent to a planning computer which aids in the determination of the pre-surgical plan. This planning computer may be located back at the original local hospital, or it may exist in some other location. The planning computer may be operated by a local operator, or

the planning computer may be run by a remote expert. For example, the operators at the central location may send a patient's medical history, X-rays, 3D template bone model, and other information to a remotely located orthopedic surgeon or other expert. This expert may use that
5 information and his or her skill to generate the plan on a local planning computer, or the expert may send plan suggestions back to a planning computer at the central location. The particular expert chosen to assist in developing the plan may be based on that expert's area of expertise.

After the generated (or amended) pre-surgical plan has been
10 accepted by the surgeon, the operation is performed. During the osteotomy surgery, fluoroscopic images of the marker positions are taken and then sent electronically to the planning computer (either in the same hospital or a remote location). The surgical plan can be updated, and the results of the updated surgical plan can be sent to the local hospital where
15 the osteotomy is performed.

Because of the segmented approach to the present orthopedic surgery method, the possibilities of patient and computer locations are virtually endless. These methods provide for "remote expertise" wherein CAOS experts can oversee and run the planning computer from a central
20 location and a plurality of surgeons from different hospitals can electronically communicate with the CAOS experts. This method may include vastly reduced costs compared to present methods, and many hospitals and offices that can not afford IR tracking equipment will now be able to perform osteotomy procedures.

The above examples focused on an open wedge osteotomy as an example of an orthopedic surgery performed using the present invention. However, this invention can be used for many different types of orthopedic surgery, as well as many other types of surgical and non-surgical applications where intra-operative feedback may be helpful. For example, the present invention could also be used for closing wedge, distraction, dome, derotational, step-cut, and other types of orthopedic surgery. With these surgeries, the basic framework of the invention remains constant, but the exact plan and surgical tools used to implement the invention may be altered.

The present invention may also be used for a total joint replacement, such as a hip or knee replacement. For example, if the hinge surface of a patient's knee is worn out, the surgeon may cut the lower portion of the femur and the upper portion of the tibia and insert a new knee joint into the patient's leg. To achieve surgical success, the surgeon needs to align the new knee joint with the existing bone structure of the patient. Traditionally, a series of jigs and/or alignment rods have been used. Using the multifunctional markers of the present invention, the surgeon may be able to more accurately align the new joint using a less invasive procedure than conventional methods.

The present invention may be used in cases of multiple trauma with long bone fractures. To realign the bone and minimize blood loss, the trauma surgeon uses an external fixator to quickly stabilize the patient. Thereafter, the surgeon may take a fluoroscopic or other image of

the fractures and apply the present system to obtain an exact realignment of the fractured bone.

The present invention may also be used for oncology-related applications, such as removing a bone tumor from a patient. Generally, a surgeon performing a bone tumor removal seeks to remove only the tumorous portions of the bone while leaving the healthy tissue in tact. Because visual clues are not always available to the surgeon, the present invention may be used to develop a surgical plan and place markers around the tumor sight. An updated image of the marker position may be used to easily determine which parts of the bone are tumorous and need to be removed. Also, after the surgery, the markers may be used to make sure that the complete tumor was removed. Use of the present invention is less expensive and time consuming than the conventional MRI/CAT-based methods.

The present invention may also be used to ease the performance of complicated surgeries. For example, spine surgery may be difficult because it involves a 3D surgery around the spine in an area of the body where there may be a small margin for error. The multifunctional markers and fixation devices may allow the surgery to be performed more precisely, and in a reduced amount of time.

The present invention may also be used to perform intramedullary procedures on a patient's bone. In such a procedure, a rod is inserted inside the hollow of a bone down its long axis. Near at least

one end of the rod, there is an elliptical hole that accepts a screw to prevent the rod from rotating or twisting within the bone. In conventional methods, it is often difficult to accurately locate the elliptical hole for the set screw. Using the multifunctional markers and fixation devices of the
5 present invention, localization would be more easily accomplished.

For example, the updated marker position may be used to provide settings as part of a surgical plan for a device that allows the insertion of the set screw. Rather than searching within the patient to find the elliptical hole, the surgeon can set the fixation device and insert
10 the screw with confidence that the hole will be beneath the device.

The present invention may be used in a similar manner to the above methods for performing localization and surgical procedures on bone lesions, any soft tissues, and/or maxilo-facial surgery. In general, the embodiments and features of the present invention may be specifically
15 suited to aiding in the performance of many or all bone and soft tissue procedures.

The above specification describes several different embodiments and features of a device and method for performing orthopedic surgery. Various parts, selections, and/or alternatives from the
20 various embodiments may preferably be interchanged with other parts of different embodiments. Although the invention has been described above in terms of particular embodiments, one of ordinary skill in the art, in light of the teachings herein, can generate additional embodiments and

modifications without departing from the spirit of, or exceeding the scope of, the claimed invention. Accordingly, it is to be understood that the drawings and the descriptions herein are proffered only by way of example only to facilitate comprehension of the invention and should not be

5 construed to limit the scope thereof.

WHAT IS CLAIMED IS:

1. A method of providing a computer-aided surgical plan, comprising the steps of:
 - generating a computer-aided pre-surgical plan including
5 settings for at least one manually adjustable surgical tool;
 - accepting intra-operative feedback from a surgeon; and
 - generating a computer-aided final surgical plan based on the pre-surgical plan and the intra-operative feedback.
2. The method of claim 1, wherein said at least one
10 manually adjustable surgical tool comprises an adjustable cutting guide.
3. The method of claim 1, wherein said at least one manually adjustable surgical tool comprises an adjustable fixation guide.
4. The method of claim 1, wherein said at least one manually adjustable surgical tool comprises a combined cutting-fixation
15 guide.
5. The method of claim 1, wherein said intra-operative feedback comprises an image of a patient taken during surgery.
6. The method of claim 5, wherein said image is an X-ray.

7. The method of claim 5, wherein said image is a fluoroscopic image.

8. The method of claim 7, wherein said fluoroscopic image includes a set of calibration grid points used to unwarp the
5 fluoroscopic image.

9. The method of claim 1, wherein said at least one manually adjustable surgical tool is directly attached to an area of a patient wherein a surgical procedure is being performed.

10. A method of providing a computer-aided surgical plan,
10 comprising the steps of:

creating a computer-aided three-dimensional model of an area of a patient upon which a surgical procedure will be performed; and

determining a pre-surgical plan for performing said surgical procedure based on said three-dimensional model, wherein said surgical
15 plan includes the placement of at least one multifunctional marker.

11. The method of claim 10, wherein said at least one multifunctional marker is radio-opaque.

12. The method of claim 10, wherein said at least one multifunctional marker is capable of anchoring a surgical device to the
20 area of the patient upon which the surgical procedure will be performed.

13. The method of claim 10, wherein said placement of at least one multifunctional marker includes a range of acceptable marker placement positions.

14. The method of claim 10, wherein the step of
5 determining a pre-surgical plan is further comprised of determining an optimum location for an osteotomy.

15. The method of claim 10, wherein the step of determining a pre-surgical plan is further comprised of determining settings for a surgical device affixed to said multifunctional markers.

10 16. The method of claim 15, wherein said surgical device is a combined cutting-fixation guide.

17. The method of claim 15, wherein said surgical device is a calibration grid.

18. The method of claim 10, further comprising the step of:
15 updating said pre-surgical plan into a final surgical plan based on information obtained during the surgical procedure.

19. The method of claim 10, wherein the step of determining a pre-surgical plan for performing said surgical procedure includes a numerical analysis of said computer-aided three-dimensional
20 model.

20. The method of claim 19, wherein said numerical analysis is iterative.

21. A method of remotely providing a computer-aided surgical plan, comprising:

5 receiving initial medical information from a remote source;

generating a computer-aided pre-surgical plan for performing a surgical procedure at said remote source;

receiving updated medical information from said remote source during the surgical procedure;

10 generating a computer-aided final surgical plan for completing said surgical procedure.

22. The method of claim 21, wherein said initial medical information includes at least two X-ray images of a patient.

23. The method of claim 22, wherein said images are
15 orthogonal to each other.

24. The method of claim 21, wherein said updated medical information includes a fluoroscopic image of a patient.

25. A method of remotely providing a computer-aided surgical plan, comprising the steps of:

receiving initial medical information from a first remote site;

selecting a surgical expert in a second remote location based
5 on said initial medical information;

receiving a pre-surgical plan from said remote surgical expert;

sending said pre-surgical plan to said first remote location;

receiving updated medical information from said first remote
10 location during a surgical procedure;

determining a final surgical plan based on said updated medical information; and

sending said final surgical plan to said first remote location.

26. The method of claim 25, wherein said step of
15 determining a final surgical plan is comprised of:

sending said updated medical information to said remote surgical expert; and

receiving said final surgical plan from said remote surgical expert.

27. A method of using a computer to determine a surgical plan, comprising the steps of:

5 generating a three dimensional computer model of an incorrectly aligned bone;

performing a numerical analysis on the computer model of the bone to determine a plurality of possible surgical plans; and

selecting one of said plurality of possible surgical plans.

10 28. The method of claim 27, wherein said numerical analysis is an iterative analysis.

29. The method of claim 27, wherein said step of performing a numerical analysis comprises the steps of:

15 virtually cutting the computer model of the bone at a plurality of locations along the long axis of the bone;

repositioning the computer model of the bone along a desired mechanical axis; and

calculating the deviation between the original and final positions of the computer model of the bone before and after said step of repositioning the computer model of the bone.

30. The method of claim 27, wherein said step of
5 performing a numerical analysis comprises the steps of:

virtually cutting the computer model of the bone at a plurality of first locations along the long axis of the bone;

repositioning the computer model of the bone along a desired mechanical axis;

10 calculating a first deviation between the original and final positions of the computer model of the bone before and after said step of repositioning the computer model of the bone;

for each of said plurality of first locations, virtually cutting the computer model of the bone at a plurality of second locations along the
15 long axis of the bone;

performing a second repositioning of the computer model of the bone along the desired mechanical axis;

calculating a second deviation between the original and final positions of the computer model of the bone before and after said step of
20 repositioning the computer model of the bone; and

determining, with the aid of a computer, the first and second virtual cutting locations corresponding to a minimum combined first and second deviations.

31. A system for providing a surgical plan, comprising:

5 a database of three dimensional template bone models;

a modeling computer electronically connected to the database for creating a three dimensional model of an incorrectly aligned bone; and

a planning computer for generating a surgical plan.

32. The system of claim 31, further comprising a computer
10 near an operating room, wherein said planning computer and operating room computer are connected through an electronic communications network.

33. The system of claim 31, wherein said electronic communications network is the Internet.

15 34. A method of providing a surgical plan, comprising the steps of:

accepting patient information from a surgeon, wherein said patient information includes information about the placement of a surgical tool on a patient; and

generating a surgical plan based on said placement
information.

Example of Malalignment

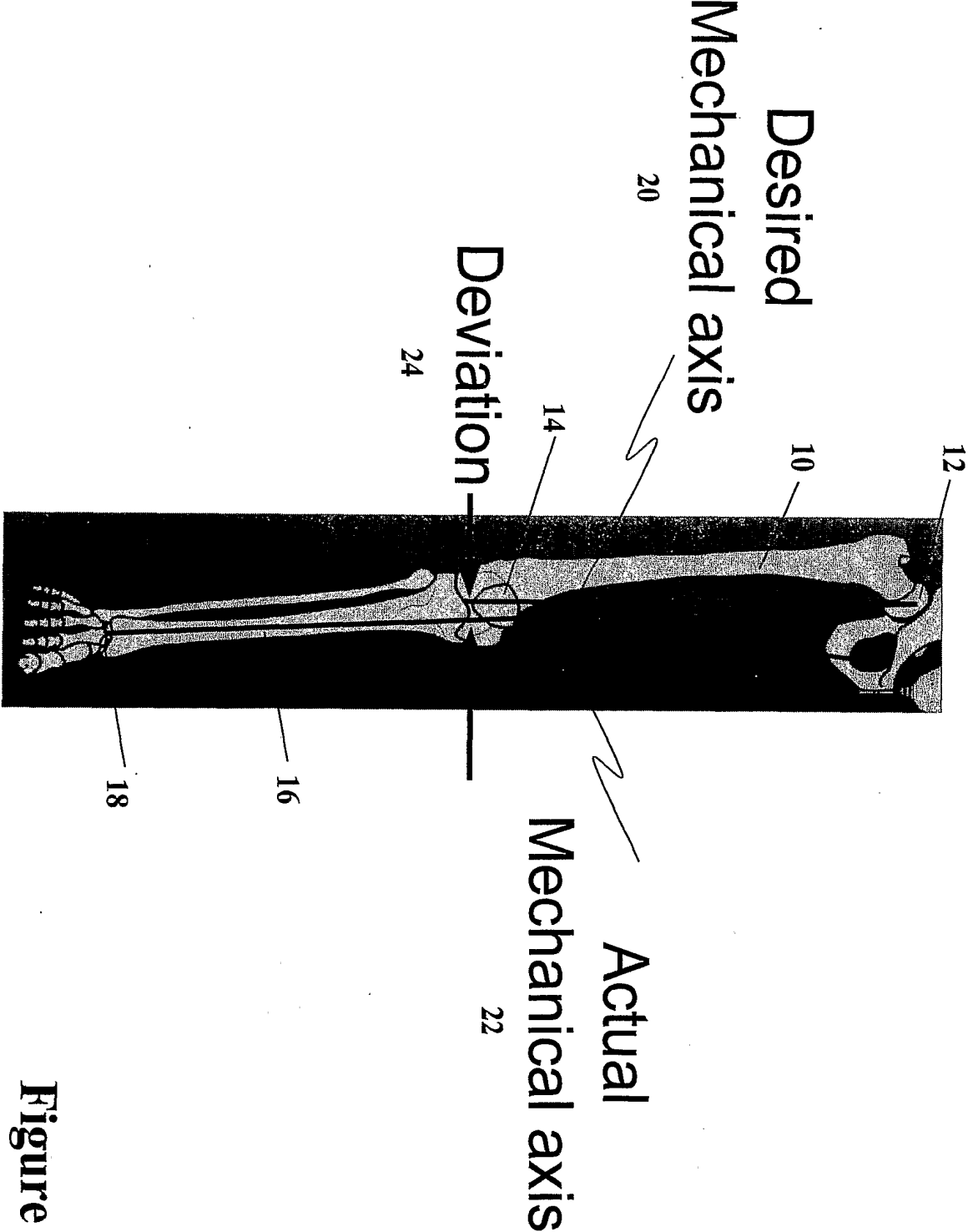


Figure 1

Computer-Aided Orthopedic Surgery (CAOS)

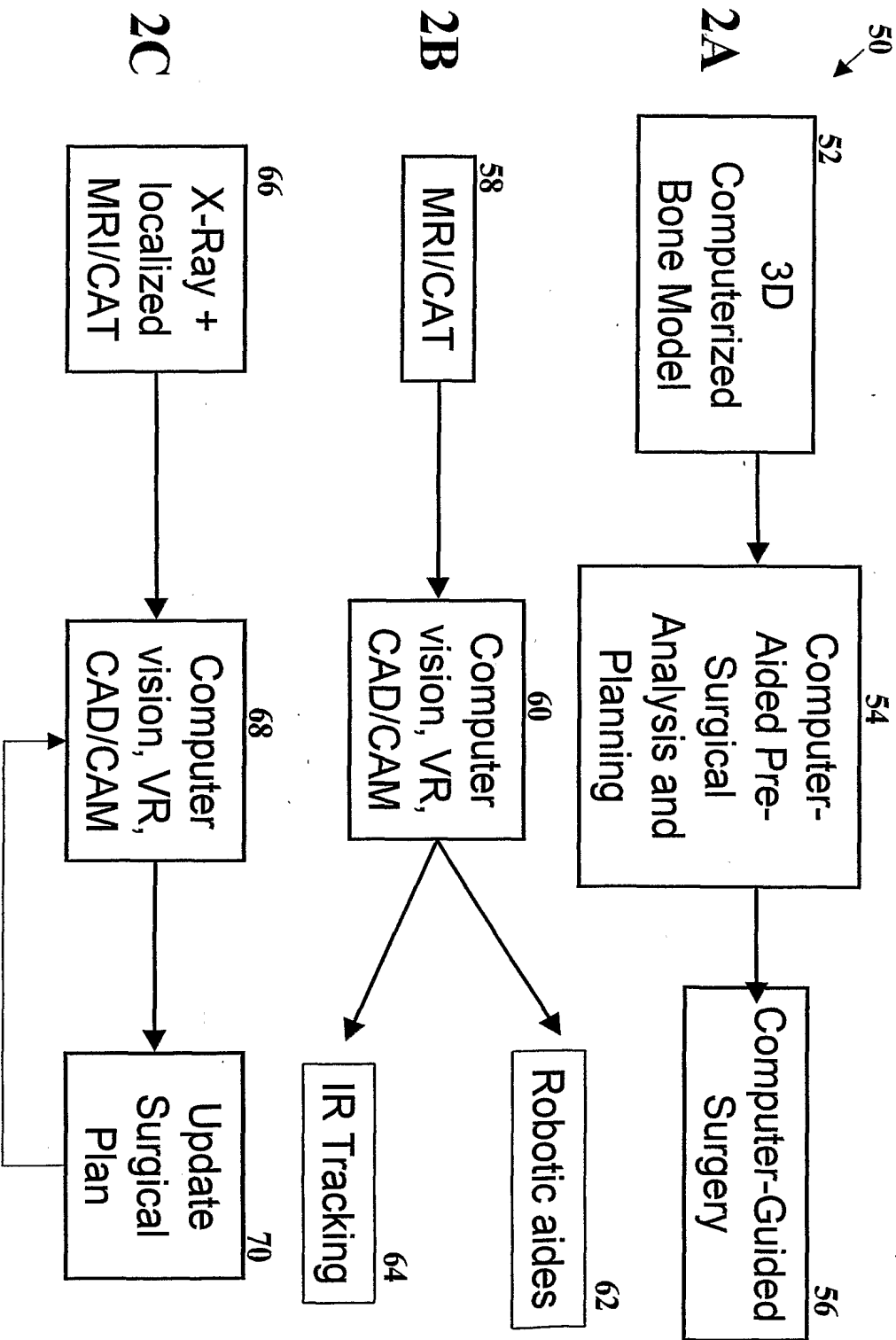


Figure 2

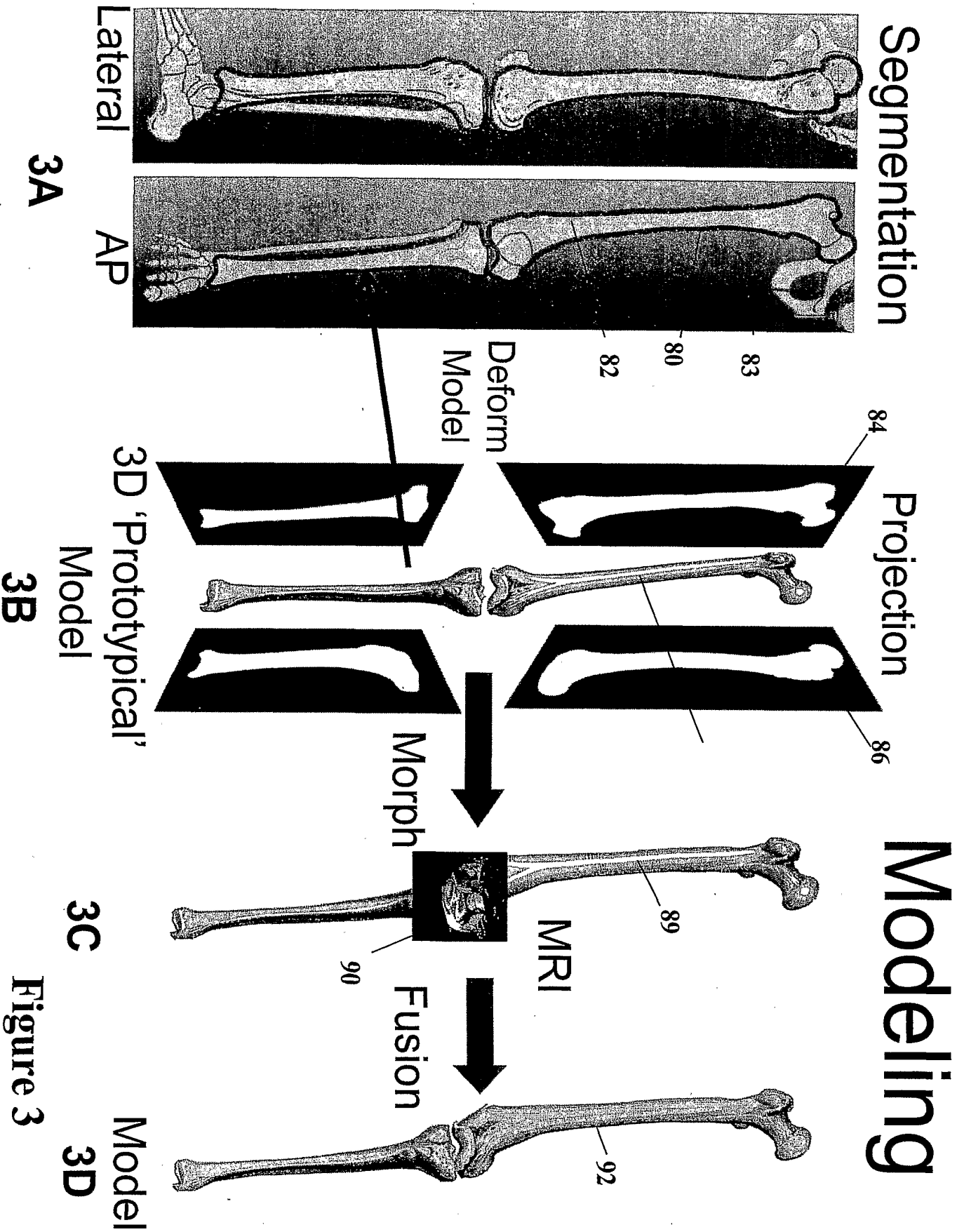


Figure 3

Presurgical Analysis and Planning

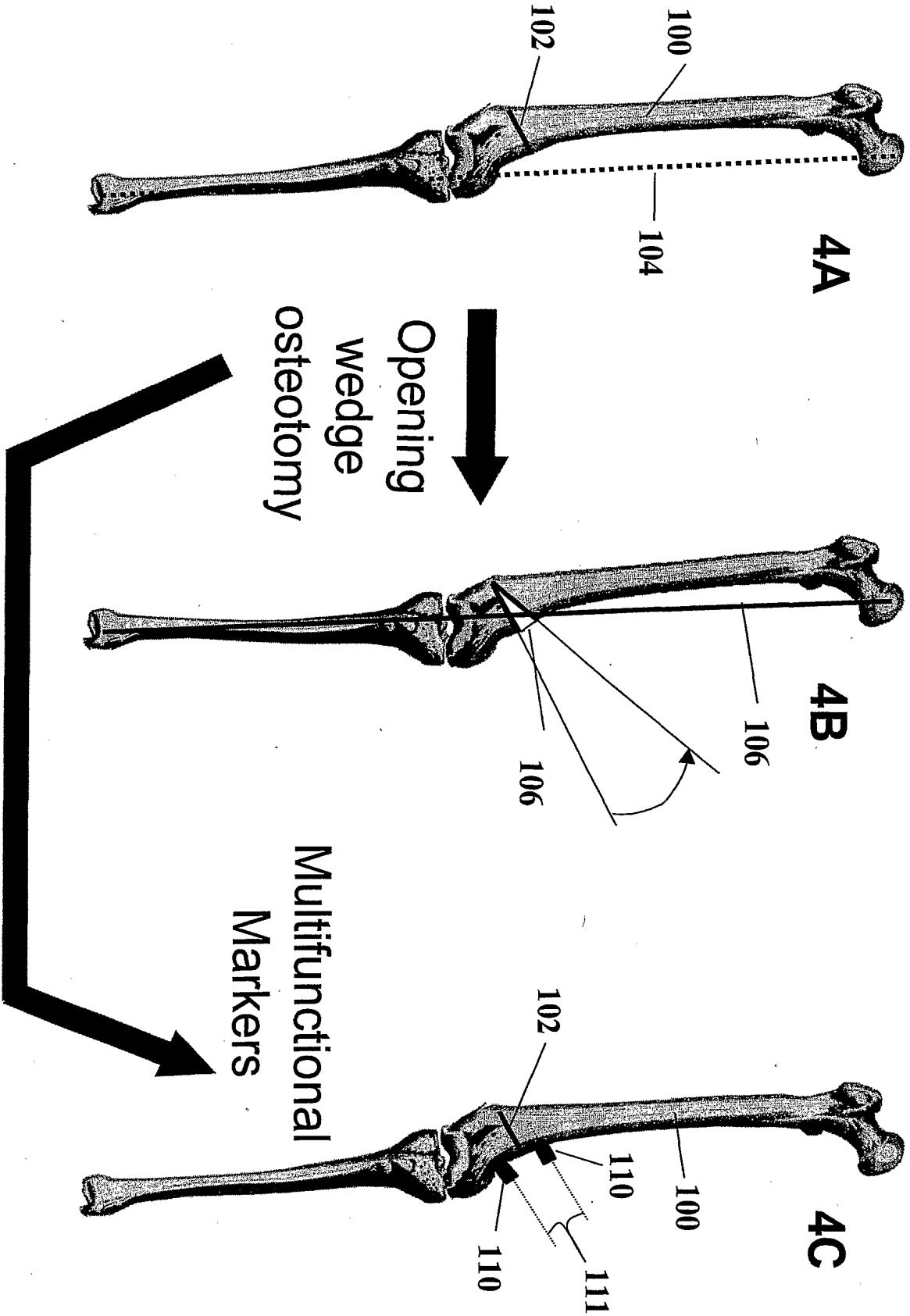


Figure 4

Offset Analysis of Single Osteotomy

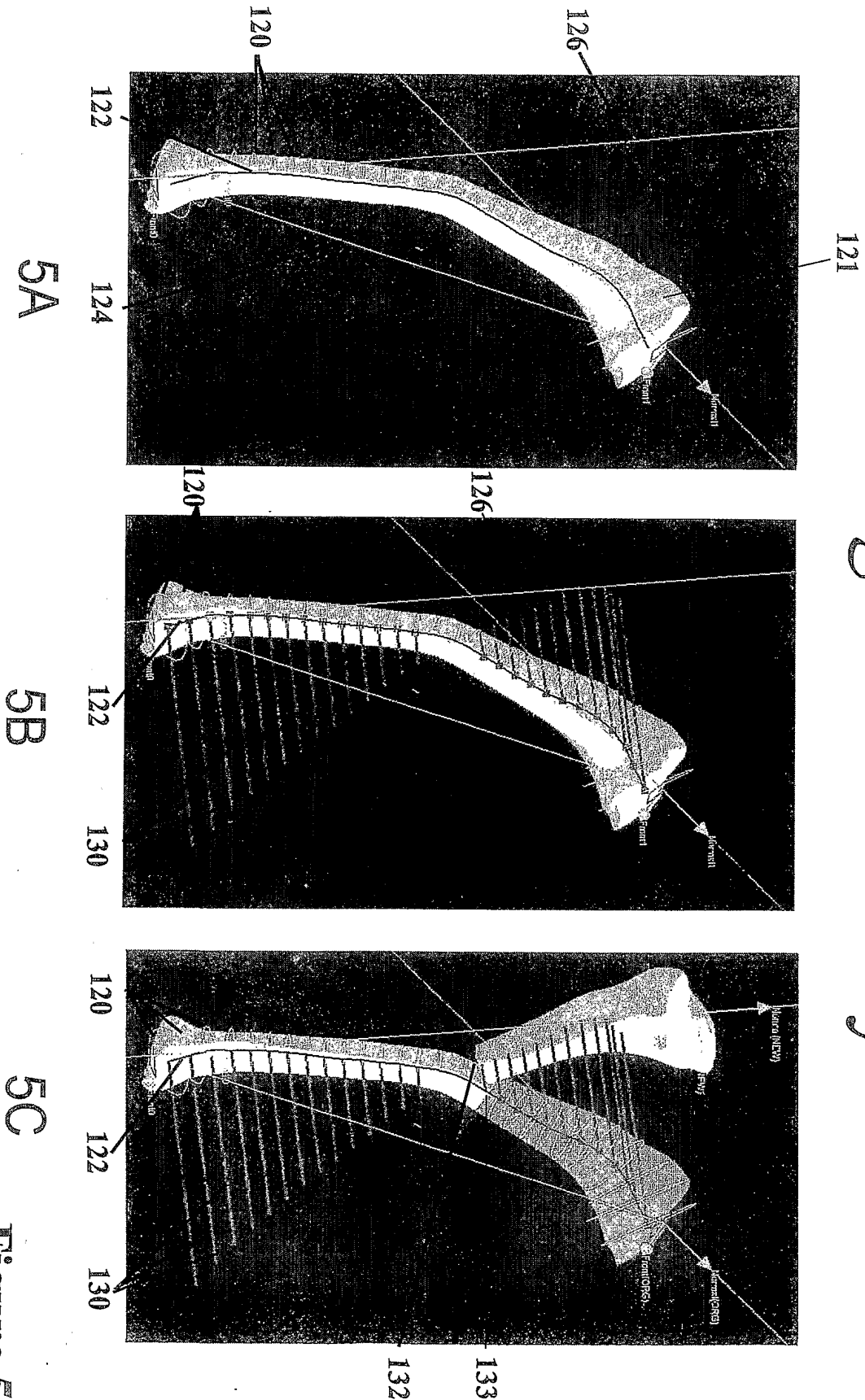
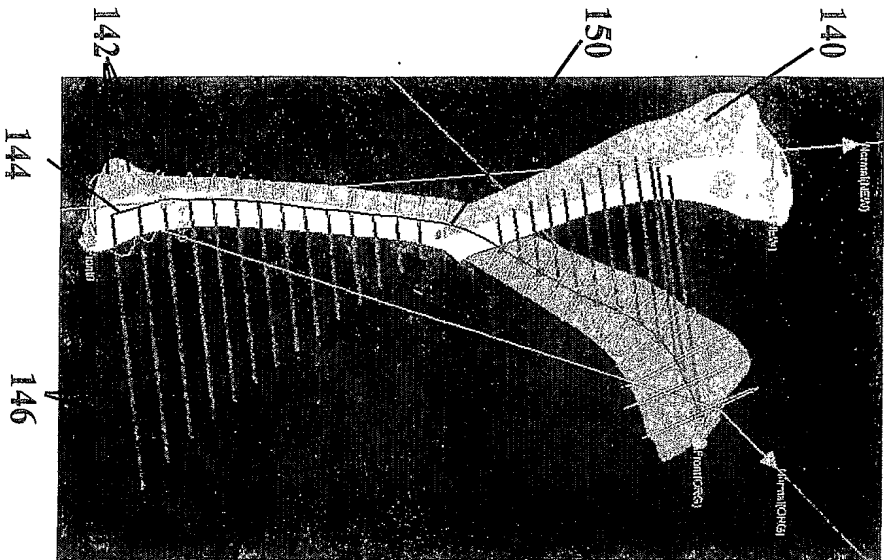
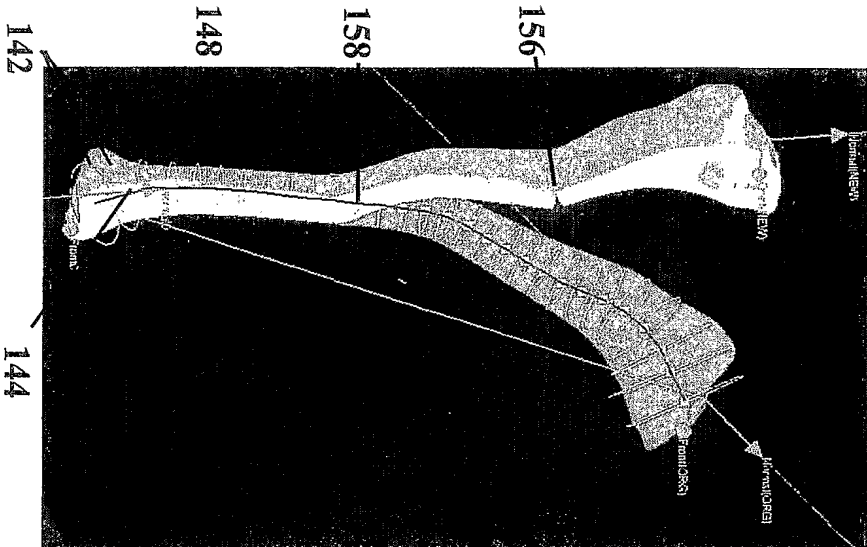


Figure 5

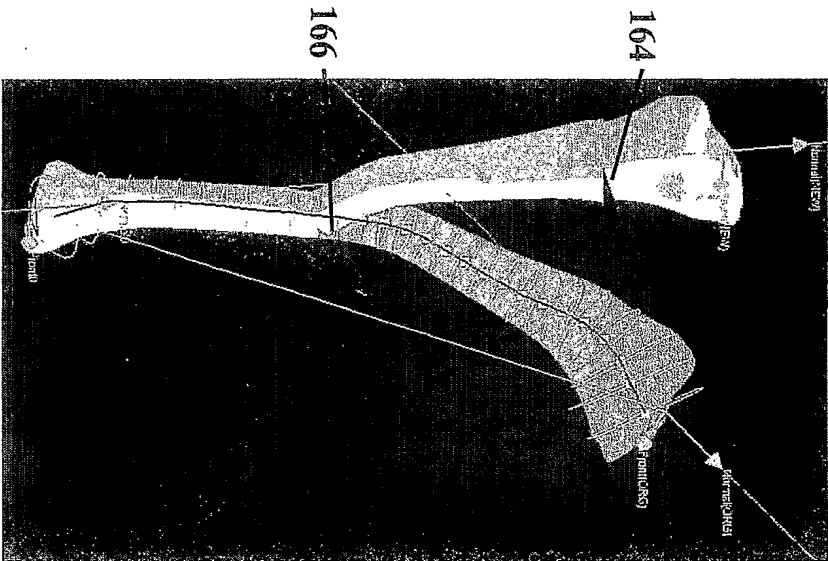
Offset Analysis of Double Osteotomy



6A



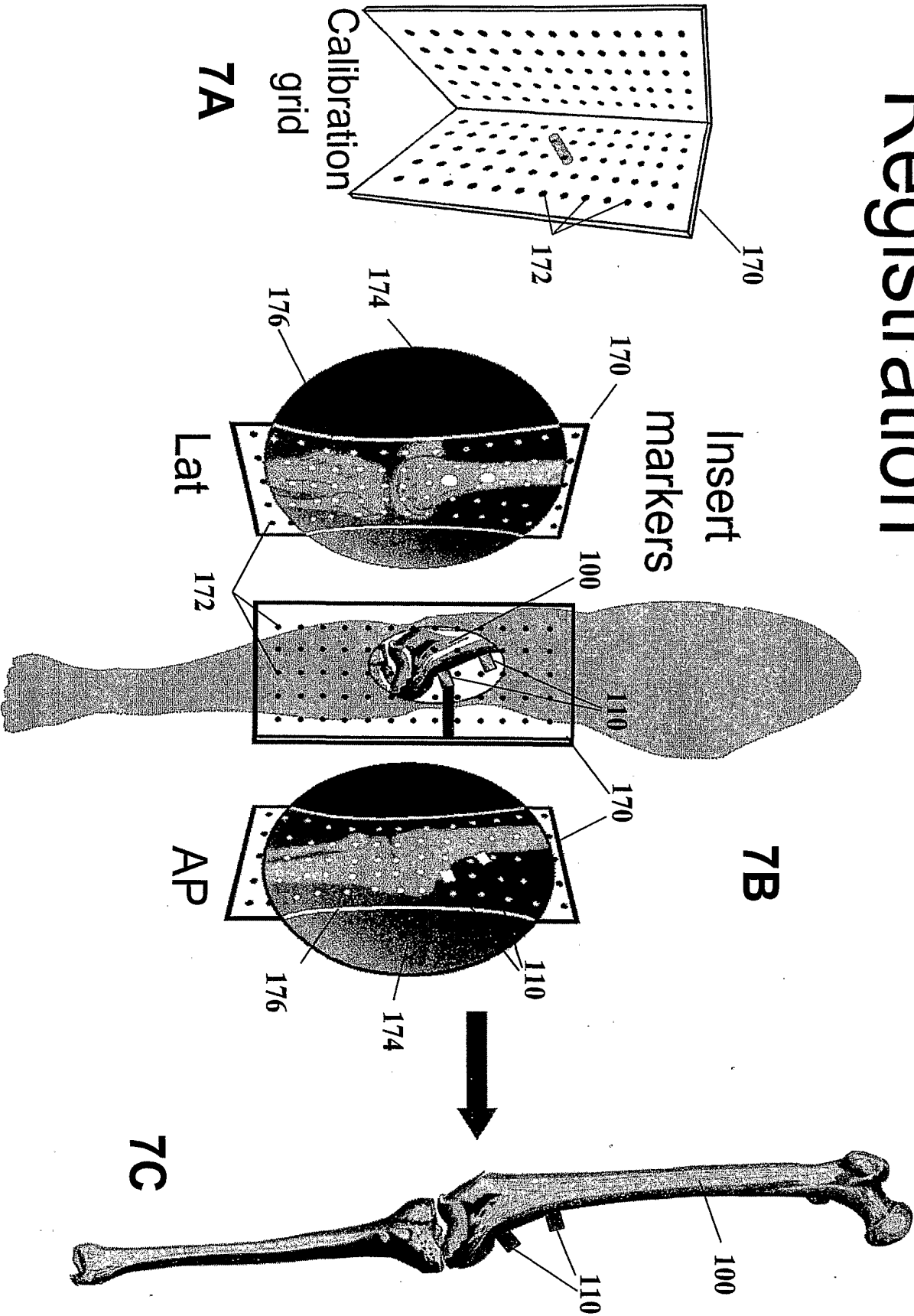
6B



6C

Figure 6

Registration



Surgical exposure

Figure 7

Adjustable Cutting Guide

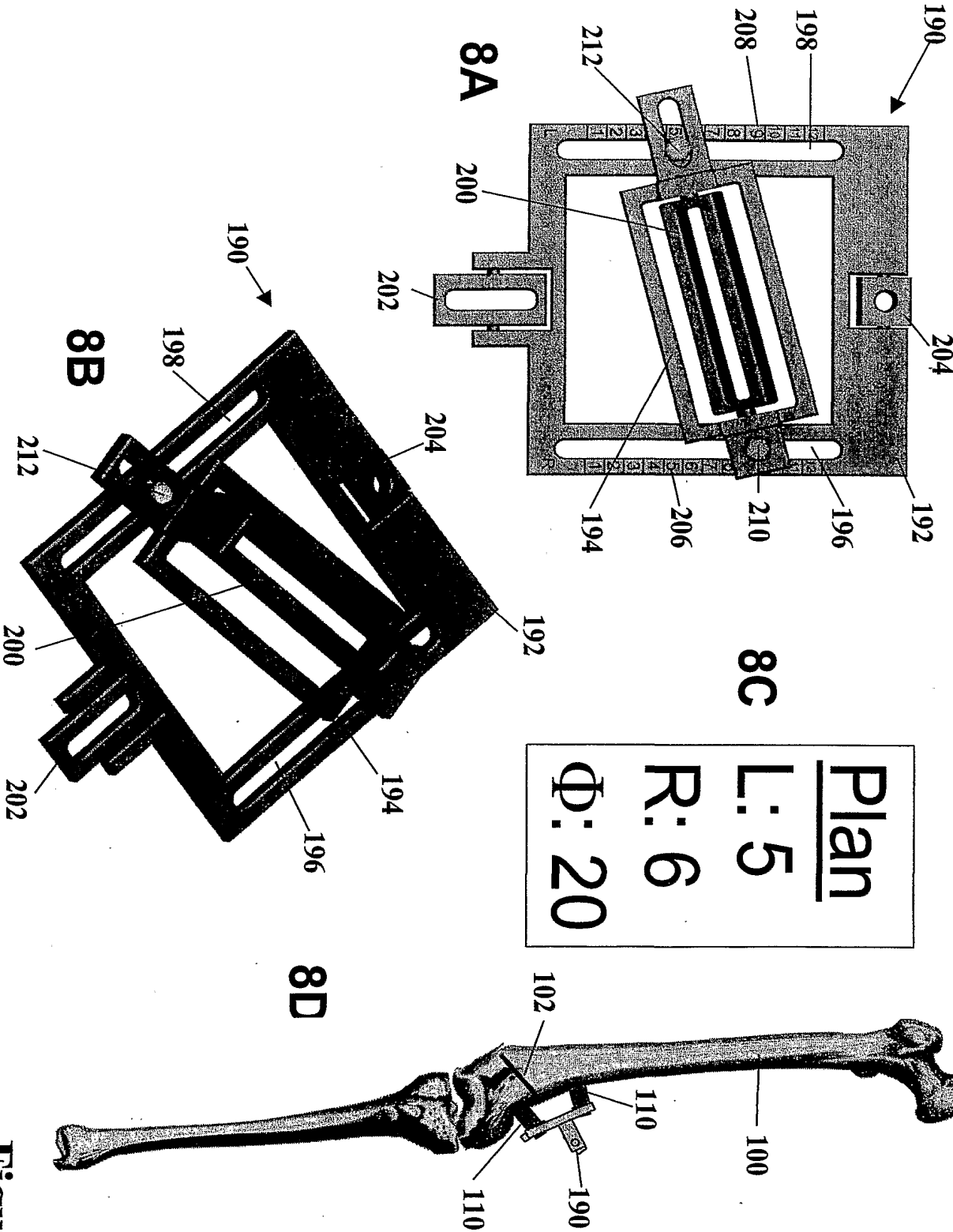


Figure 8

Opening Wedge and Execution

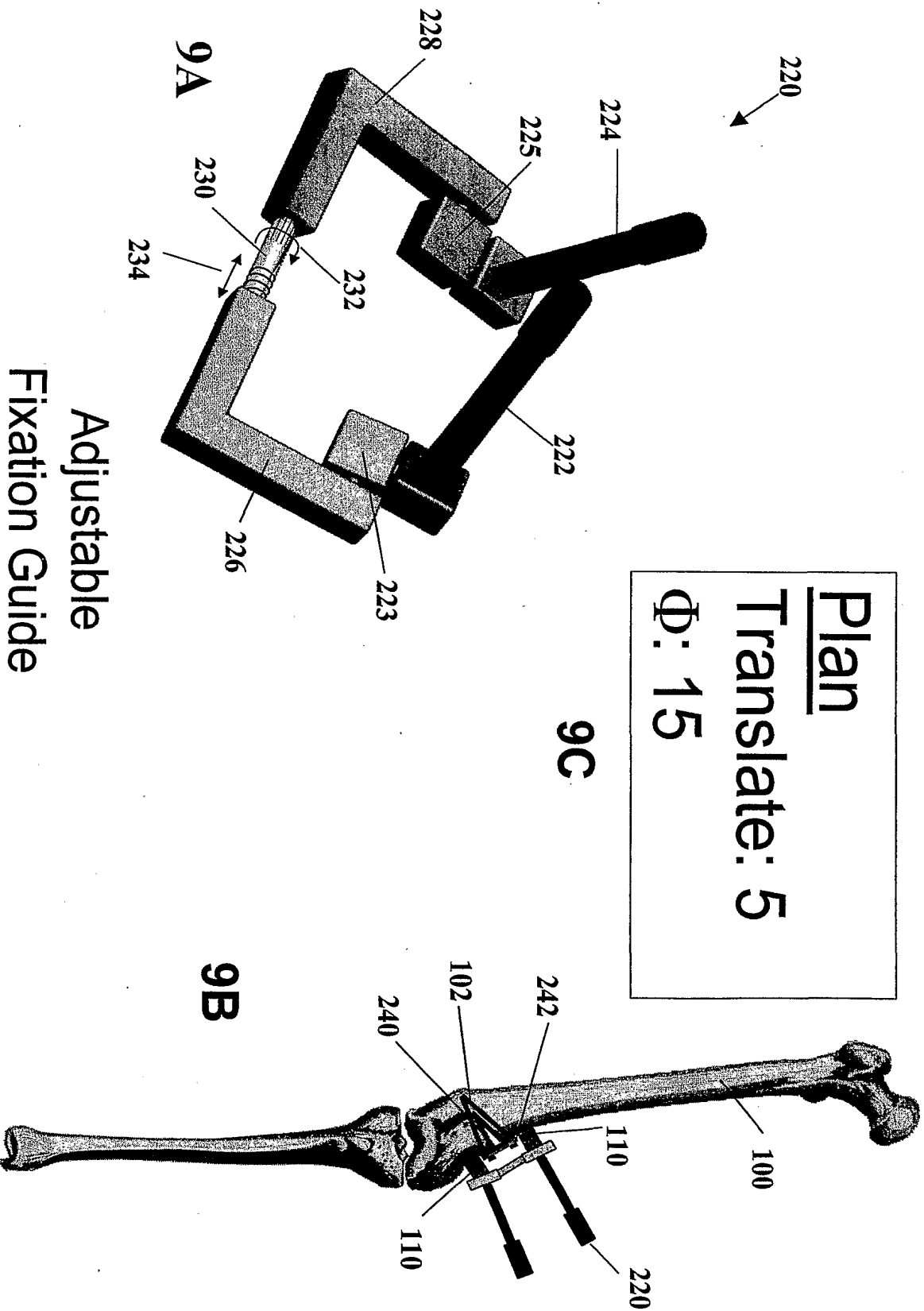


Figure 9